Ministry of Agriculture, Fisheries and Food

Report of the Committee on the Ethics of Genetic Modification and Food Use

LONDON: HMSO

Ministry of Agriculture, Fisheries and Food

Report of the Committee on the Ethics of Genetic Modification and Food Use

LONDON: HMSO

First published 1993

ISBN 0 11 242954 8

The Rt Hon Gillian Shephard MP, Minister of Agriculture, Fisheries and Food.

Madam,

I have the honour to present the Report of the Committee on the Ethics of Genetic Modification and Food Use.

Our method has been to seek advice and information from as many groups and traditions as possible. No absolute consensus emerged on most of the questions our inquiry had raised. Yet it was clear that there were a variety of ethical concerns relating to the use of genetically modified organisms as food, which should be taken into account in framing public policy. The aim of our recommendations is to make practical provision for informed choice by consumers in accordance with their individual ethical insights.

We are pleased that we are able to present a report agreed unanimously by all the members of the Committee. As its Chairman, I would like to record my gratitude to my colleagues for their hard work and co-operative spirit. We record our thanks to our Secretariat, Mr Timothy Davis and Miss Sara Grinnell. We could not have accomplished our task without their untiring and valuable assistance.

John Polkinghorne

ANNEXES

1. INTRODUCTION AND TERMS OF REFERENCE

Background

1.1 In 1990 the Advisory Committee on Novel Foods and Processes (ACNFP) received a submission concerning sheep modified to carry a human *gene.** The gene coded for Factor IX, a *protein* involved in blood clotting which is required in the treatment of haemophiliacs. The purpose of the programme was to develop a cheaper and potentially safer source of the factor which currently has to be obtained from human blood. At that stage the company involved had no interest in selling the potentially highly valuable animals carrying the human gene. However, for commercial reasons, they wished to be able to market the large majority of animals in which modification had not been accomplished.

1.2 This submission caused the ACNFP to address the wider question of the safety of using, as food, farm animals from *genetic modification* (GM) programmes involving human genes. The Committee concluded that for certain categories of animals produced by these programmes it was possible to determine unequivocally that the intended modification had not been achieved. In such cases, the animals were perfectly "normal" and so raised no food safety concern. For animals where modification had succeeded the Committee considered that the safety of such *transgenic* animals for food use would have to be considered on a case-by-case basis.

1.3 However, it was clear to the ACNFP that there were ethical issues beyond those simply of safety which might arise from the marketing and consumption of animals derived from genetic modification programmes. In response to this and related concerns in September 1992, the Minister of Agriculture, Fisheries and Food appointed this Committee.

Terms of Reference

1.4 Our terms of reference were:

> **"to consider future trends in the production of transgenic organisms; to consider the moral and ethical concerns (other than those related to food safety) that may arise from the use of food products derived from production programmes involving such organisms; and to make recommendations."**

Scope of the Study

1.5 In our consultation letter (**Annex C**) inviting views we identified a number of potential areas of development which could give rise to ethical concerns relating to food use:

— the transfer of human genes to food animals (such as the sheep discussed above);

Note*: Technical terms in this report are shown in italics when used for the first time and described in the glossary at **Annex I.

— the transfer of genes from animals whose flesh is forbidden for use as food by certain religious groups (e.g. pigs for Muslims and Jews), to animals which they normally eat;

— the transfer of animal genes into food crops, which may be of particular concern to some vegetarians (especially vegans);

— the use of *organisms* containing human genes as animal feed (e.g. yeast modified to produce human proteins of pharmaceutical value and the spent yeast then used as animal feed).

1.6 The issues raised by our review are discussed in subsequent chapters. However, a number of points were put to us which were not within our remit. Our terms of reference quite explicitly excluded the question of the **safety** of foods produced by genetic modification since this is a matter for the ACNFP. Neither were we asked to consider the wider question of the ethics of genetic modification in itself. We recognise that a series of ethical issues have been raised in connection with this new technology. Some relate to the nature of the technology and others to its consequences, for instance for the environment. There is also the issue of the propriety of the ownership or patenting of life forms. Our concern, however, is with the "**food use**" issue alone and not with these wider matters. They are being looked at by others, at least, in part. In particular the Minister of Agriculture, Fisheries and Food has recently announced the establishment of an ethical inquiry into Novel Animal Breeding Techniques.*

1.7 Furthermore we are concerned with the question of consumer attitudes to genetically modified foods **only** to the extent that any arise from ethical considerations. More general issues are being addressed by the Food Advisory Committee (FAC) in their deliberations on the labelling of such foods.

1.8 Although we do not generally consider wider ethical matters, there are two such issues which do have a bearing on our considerations because it has been suggested to us by some that they are sufficiently serious to induce a "moral taint" to the products of genetic modification which carries over to make their food use ethically unacceptable.

1.9 By "moral taint" we mean that moral revulsion at the process is such that no reasonable person would consider consuming the food produced by it. An example of this concept from another area is that many would find it unacceptable to use, for transplant purposes, the organs of a prisoner who had died under torture. The first of the "moral taint" concerns expressed to us relates to the nature of the technology. In conducting this study it has become apparent that for some groups or individuals there exists a degree of unease about the "unnaturalness" of the process, although only one group responding to our consultation went so far as to call for a moratorium on genetic modification. We discuss this issue in detail in Chapter 3. However, at this stage we note that certain groups or individuals are opposed to, or have strong reservations about, genetic modification in principle.

1.10 The second concern relates to the possible animal welfare implications attached to the process. Certain groups argue that any suffering caused to animals in the production of food renders such food ethically unacceptable to them, however minor the suffering involved may be. Such people would regard as "tainted" any food

---

*Ministry Agriculture, Fisheries and Food, News Release No. 150/93 of 5 May 1993.

produced by genetic modification if animals were used in any way in its production or testing.

1.11 We have given serious consideration to these representations, but we are unable to accept the existence of a "moral taint" that would warrant a total ethical prohibition on *GM food* use. Our position on this issue is influenced in particular by the "**dilution effect**" argument and our views on the status of *transgenes,* both of which are described in Chapter 2. While there are ethical anxieties about aspects of genetic modification, a total ban would require the judgement that the whole process was morally defective. Only a minority appear to take this view and we are unable to share it.

1.12 As noted above, the Committee was not concerned with the safety of genetic modification or of genetically modified food. Neither were we concerned with the animal welfare issues arising from the production of transgenic animals. However, both these matters are of some interest as background to our report and a brief outline of the legislation and other controls in these areas is included in **Annexes A and B.**

Method of Working

1.13 The Committee met for the first time in December 1992 and has met five times. We invited written submissions from a wide range of interests at the outset of our deliberations. A copy of our consultation letter is at **Annex C.** We received submissions from those listed in **Annex D** and are grateful to all of them for their contributions. We also met and discussed the issues in greater depth with those organisations listed at **Annex E.**

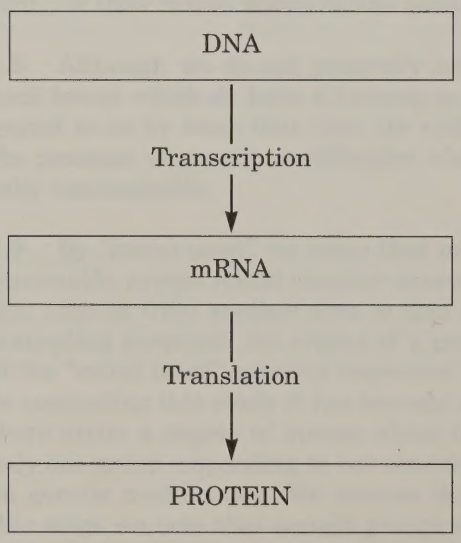
2. GENES AND GENETIC MODIFICATION: A BASIC GUIDE

General

2.1 This section discusses some of the background issues relevant to the report. Since the report is aimed at a general audience it has deliberately been written in lay terms and focuses on those issues which are relevant to the subject matter under consideration. As previously indicated, where technical terms are unavoidable, they are shown in italics and explanations are contained in the Glossary at **Annex I.**

Genes

2.2 Every organism contains its own "blueprint" in its genes, the basic units of *heredity.* Genes are located in *chromosomes* and the chromosomes themselves are present in every *cell* of an organism. All chromosomes have the same basic structure: a very long *DNA molecule* supported by special proteins. The sequence of chemical sub-units (*nucleotides*) in a DNA molecule forms a coded message which is translated into *messenger RNA* which, in turn, defines which *amino acids* are used to make up the various proteins which the organism needs in order to develop. This process is illustrated diagrammatically in **Figure 1.** Each sequence of three nucleotides codes for one of the 20 amino acids that make up proteins. This coding has meaning and consequence only within the total biochemical environment of a living cell. In isolation, DNA is merely a highly complex chemical substance.



The information contained in the DNA sequence of a gene is copied into messenger RNA (mRNA) in a process known as transcription.

The mRNA then directs the production of a specific protein in a process known as translation. The structure of the mRNA is "read" by the cell's protein manufacturing machinery. Amino acids are assembled in a specific order to produce the protein originally specified by the gene.

Figure 1. DNA, RNA and proteins.

2.3 It has been estimated that human cells contain between 50,000 and 100,000 different genes. With a few exceptions the same genetic material (*genome*) is present in all the cells of a multi-cellular organism. Cells of a particular organism differ widely in type not because they contain different genes but because different genes are, have been, or will be, active in different cells of the same organism.

Genetic Modification

2.4 Genetic modification involves changing genes and the way they are combined together. In a broad sense modification has always occurred in nature, allowing species to evolve and adapt to their changing environment over a period of years. It is also the basis of *selective breeding* of animals and plants which has been carried out for centuries. However, scientific techniques now allow the insertion and deletion of particular genes in a much more controlled manner. Equally fundamentally, they allow the transfer of genes between species in a way that would not occur in nature because interbreeding would not result in viable offspring.

2.5 In principle it is becoming possible to identify a gene (or collection of genes) that codes for a particular desired characteristic (e.g. disease resistance), extract that gene and insert it into the *host* (*micro-organism*, plant or animal) that is to be modified. No longer do the donor and the host need to breed with each other. It is also possible to render inactive particular genes. In practice only a limited number of modifications have been accomplished, but in theory current techniques could move any gene between any two organisms.

2.6 The actual processes involved in carrying out genetic modification are varied and highly complex. However, in outline, the process is relatively straightforward. Five basic steps are involved – the DNA from a cell of the organism donating the gene is broken down and the pieces separated; the required gene is located; the gene is copied many times; the copies are introduced into the organism that is to be modified; and finally the modified organism has to be identified. As the frequency of successful modification is generally low, the same modification procedure is usually carried out on a number of organisms simultaneously. The organisms which have been modified then have to be selected and separated from those which remain unmodified.

2.7 A variety of techniques is available for the introduction of genes into different organisms. These include the use of *vectors,* which can be *viral* or *bacterial,* or physical methods, such as "biolistics" (bombardment with high-velocity gold or tungsten particles coated with DNA) and "electroporation" (the use of an electrical voltage to make the cell membrane permeable to DNA). For animals *micro-injection* into the fertilised embryo at the single cell stage is usually employed. Treated embryos are then transferred into a surrogate "mother" where they develop. After birth the offspring are checked to see if they have been modified successfully.

The "Dilution Effect" and the Status of Genes

2.8 It follows from the nature of the technique that when a transgenic animal is described as containing "human" genes, this reflects the fact that it contains copies of a gene originally obtained from this source. It thus reflects its origin and structure and not its immediate source. It is not technically possible to take a gene directly from a human cell and insert it into host material such as a sheep embryo. As illustrated in **Annex G** a series of *in vitro cloning* and amplification steps have to be undertaken to prepare genetic material suitable for insertion into a new host. The result of this process is that the original "human" gene is "diluted" to the extent that the chance of the original gene taken from human cells being present in the sheep embryo is vanishingly small. **The chances of recovering the original human gene from the sheep embryo are much less than the chances of recovering a specific drop of water released into the oceans of the world.** As a consequence what is present in each cell of a modified sheep is not a "human gene" but a **"copy**

gene of human origin". We use this latter term in the remainder of this report to distinguish human transgenes from human genes in a human being.

2.9 A very widely used cloning technique involves the use of donor mRNA rather than donor DNA. This technique which involves the use of *complementary DNA* (cDNA) is described in **Annex H.** From the viewpoint of this study its essential feature is that the donor material (mRNA) is destroyed in the preparation of the DNA to be inserted into the host organism. This removes even the remotest possibility that the modified organism could contain genetic material directly derived from the donor.

2.10 A further consideration is that **genes fulfil their biological role only by their activity within the cell of an organism**. Some, therefore, regard genes not associated with a functioning organism largely as chemicals without special ethical status. When introduced into the **context** of a new organism the status of the gene can be considered to be that of the new organism. Others, however, do not accept this view and consider that a copy gene of human origin retains its human nature and hence its ethical status even when introduced into another animal or plant. We shall return to this issue later, but it is important to note the possible significance of context.

Gene Structure and Expression

2.11 It might be assumed that since different species appear so dissimilar their genes too would be markedly different. In fact this is often not the case. Genes producing important proteins that are common to different animal species are often remarkably similar; for example the *insulin* and IGF 1 (*insulin-like growth factor*) genes are virtually identical in sheep and humans. Of course, when genes are so nearly identical this raises the question of whether they can be considered peculiarly "sheep" or "human" in nature.

2.12 It is now possible to synthesise genes in a test tube. Normally genes used in modification are derived by copying a gene extracted from the donor organism. However, if the sequence of a gene is known it is possible to construct the gene by chemical synthesis. If this process is adopted it raises the question of whether a synthetic "human gene" should carry the ethical status of a gene derived from a human.

2.13 When a transgene is introduced into a recipient species this is normally as part of a construct (or sequence of genetic material) which includes sequences that act like a switch to control their "*expression*". This means that the transgene can be effectively programmed to be active (i.e. code for protein production) only in a particular organ of the host. Thus, for example, in the modified sheep referred to in Chapter 1, the human Factor IX gene is present in every cell. However, "human-like" protein is produced only in the mammary glands and secreted into the milk. Similarly, certain plants have been modified so that bacterial genes producing toxins which act as pesticides are active only in the leaf or the stem of the plant, but not in the edible parts.

Purposes

2.14 The purpose of modification, as with selective breeding, is to develop micro-organisms, plants or animals with new characteristics. In this report we are concerned with two types of development. Firstly, the use of copy genes of human origin in farm animals, which is likely to be principally for medical purposes. The use of

the modified animals as food is a by-product of this. Secondly, and much more commonly, modifications involving copy genes of animal or plant origin, which are likely to be undertaken for agricultural or food quality purposes.

2.15 The majority of genetic modification research currently taking place involves plants, largely because of their technical suitability and their importance as food crops. For example, there is considerable interest in developing pest- and disease-resistant varieties of cereals and other major crops. Animals too may be modified. Examples would be to produce leaner meat with the aim of decreasing dietary fat intakes or to introduce disease resistance and reduce the use of chemical treatment. A fuller summary of the likely future developments involving genetic modification for food purposes is given in Chapter 6.

2.16 In this report we concentrate attention on modifications likely to give rise to particular ethical concerns. We would emphasise, however, that many modifications will probably involve transfers of single genes between the same or closely related species. We do not want to create the impression that the wholesale shuffling of genes around the animal and plant kingdoms is imminent.

Effects of Processing and Cooking

2.17 The presence, or absence, of functional genetic material is likely to determine attitudes to the acceptability of particular GM foods. Tests have demonstrated that mild food processing techniques such as making puree or paste from fruit, will have a negligible effect on the state of the DNA. However, subjection to high temperatures, for example in making jam from GM strawberries or canning food, would degrade the DNA into non-functional components.

Fate of the Transgenes

2.18 Concern may be occasioned by the fear that ingested genes might somehow become part of an individual's own genetic make-up. There is a safety dimension to this issue which has been considered by the ACNFP. It concluded that it was most unlikely that foreign DNA from the diet could become integrated into the gut cells of its consumer. DNA in the diet is broken down by digestion which reduces the chances that an intact gene, with the control sequences necessary for its functioning, would be available intact for uptake and integration. In addition, the cells which line the gut are constantly renewed and any cell that did take up such a gene would need to have acquired a considerable selective advantage, in terms of survival, replication and colonisation, for the altered cell type to become established. Even should this unlikely event occur, such cells would not enter the *germ line* and would not therefore be maintained or spread in the population. If there were a normal process of uptake of DNA by cells of the intestinal tract, the cells of consumers **would already be full of the genes from the various animals and plants consumed in the diet.** However, if the process of integration does occur, then the theoretical considerations based on the frequency of DNA uptake and integration by mammalian cells described in **Annex F** suggest it would be a very rare event, even in optimal conditions.

3. THE ISSUES

General

3.1 Our consultation letter identified a number of areas giving rise to potential ethical concerns. In this chapter we examine these in turn. The views summarised below have been submitted to us by representatives of a particular religious faith or other group within the community. It is, of course, possible that these views do not reflect the position of all individuals within that group. Nevertheless, we believe they are likely to be sufficiently representative to provide a broad picture of the range of ethical concerns on which our recommendations must be based. We are also conscious that public knowledge about genetic modification is relatively limited and that attitudes may change as the technology becomes more widely applied and more widely debated and understood.

3.2 There is one issue which we touched upon in the introduction, which runs across all the potential areas of concern. This relates to the perceived "unnaturalness" of the process of genetic modification and whether this results in a "moral taint" of any products derived from it. It was put to us that some individuals or communities may object in principle to the use of genetic modification as "playing God" and "interfering in nature". We received a wide range of views on this point.

3.3 Muslims believe that God has created all life forms in the "best design", which should not be altered by humans except to correct "deviations" back to their original form. Muslims see the preservation of species as of particular importance and fear the "balance" of a species may be disturbed by genetic modification. They see a distinction between the improvement of a species through "natural" *cross breeding* and through genetic modification. This position has a Qur'anic basis and is guided by a concern not to interfere in the world as created.

3.4 The Hindu and Buddhist communities share some of these reservations. Both traditions involve particular reverence for the natural world. They see evolution, and even traditional selective breeding, as consistent with this view since changes are gradual and, in that respect, more controlled and potentially reversible. However, genetic modification involves "instant" change which could result in uncontrollable and irreversible consequences.

3.5 The Bahá'í faith generally takes a rather less cautious view. Genetic modification is welcomed as a fruit of the intellect that could help alleviate hunger and suffering. However, Bahá'ís share concerns about the risks associated with rapid change.

3.6 Many, but not all, of the Christian churches or individuals who responded to our consultations expressed relatively minor concern over genetic modification. Broadly speaking, Christians hold the view that human beings have been granted power to make use of nature, though the relationship should be one of stewardship and renewal and not exploitation. In principle, therefore, genetic modification is acceptable, provided adequate safeguards exist to ensure safety and animal welfare. Sikh representatives too held this overall view. Their community is generally responsive to scientific advance, although as discussed later there are specific concerns over certain dietary issues.

3.7 The Christian view of the relationship between humanity and nature is broadly shared by the Jewish faith. Humanity is seen as having the task of using

nature for its benefit, as well as nurturing and protecting it. Judaism does not believe that naturalness is necessarily a virtue. Humanity's intervention in nature is seen as necessary, particularly if it is directed towards producing life-saving or life-prolonging products.

3.8 These views were expressed to us as general attitudes to genetic modification. However, within many communities there are significant ethical problems posed by certain specific kinds of potential modification. The **purpose** served by a particular genetic modification is also a key consideration for many. If the modification preserves or enhances human or animal life, it is welcomed. If it is seen as trivial or exploitative, it is not. On the basis of the evidence we have received, we conclude that only a very small minority of the population would object in principle to all genetically modified food on ethical grounds.

Transfer of Copy Genes of Human Origin to Other Organisms

3.9 This issue raised the most widespread concern. Some groups maintain that they would be forbidden to consume any food containing copy genes of human origin on religious grounds. In particular, representatives of the Muslim community took this view. By contrast Jewish representatives found such foodstuffs acceptable. All major religions prohibit cannibalism, but different traditions take different views of the nature and status of organisms containing copy genes of human origin.

3.10 For the Muslim, the transgene retains its human nature and remains subject to the dietary taboo. For the Jew, the host organism remains the dominant species and does not assume the character of the donor. A sheep containing a copy gene of human origin remains a sheep, because it is the animal regarded as a whole which determines its status. The host animal must remain kosher and so be both cloven-hoofed and cud-chewing, but providing modification does not alter these characteristics, there is no objection. A clear distinction is drawn between copy genes of human origin and a human gene in a human body. It is the context of the gene which imparts its ethical status.

3.11 The views of the other religious groups responding to the consultation tended to fall somewhere between these two positions. Hindu and Sikh attitudes were closer to the Muslim view. The latter acknowledged, however, that with greater understanding of the processes involved, attitudes might change, particularly in the case of synthetic "human" genes (see paragraph 3.27 below). Christian attitudes were closer to the Jewish position, although representatives felt it very likely that some individual members of their faiths would find the consumption of copy genes of human origin (albeit one such gene amongst the 100,000 or so of the host organism) objectionable.

3.12 The diversity of views amongst the religious groups was reflected more generally amongst other respondents to our consultation. No submissions took the explicit view that consuming copy genes of human origin could be equated with cannibalism. Yet some viewed it as unnatural and ethically objectionable. However, for those at the other end of the spectrum of opinion, it was a matter of little concern. Copy DNA of human origin is not different structurally from other DNA consumed in the diet. It is degraded to the same chemicals once digested and does not warrant special consideration.

3.13 A number of consumer and special interest organisations took the view that it was likely that many consumers would not want to consume any foodstuffs contain-

ing copy genes of human origin. In addition to the more focused views of the religious groups there is evidence of a more general and diffuse concern over certain types of potential modification. Such attitudes are likely to be determined by a mixture of considerations, rather than by ethical concerns alone. It was not within our remit to explore these wider concerns although, whatever their actual basis, they seem to centre on the types of modification identified in this report as occasioning particular ethical concern.

Transfer of Copy Genes of Animal Origin to Other Animals

3.14 There are various religious taboos on the consumption of certain types of meat. In particular Islam and Judaism forbid the consumption of pork and Sikhism forbids the eating of beef. Hindus are usually vegetarian but those that do eat meat do not eat beef.

3.15 In general the attitude of these groups to the consumption of food containing copy genes originating from "proscribed species" corresponded to their position on the consumption of copy genes of human origin. Muslims, Sikhs and Hindus would find such a practice objectionable, whereas Jews would not. Once again, attitudes were determined by the view taken of the introduced gene and whether or not it retained the nature and status of its origin. In the case of Islam there is an additional concern in this area concerning the integrity of species, especially in relation to animals.

3.16 In addition to the views of the religious groups, the genetic modification of food animals also raises a more general concern. This concern is more specific than the welfare concern discussed in Chapter 1, which related to the possible "moral taint" of any genetically modified organism whose production or testing involved animals. It relates to a belief that modification may be used to secure economic advantage without proper regard for animal welfare. Such a belief may in part have been fuelled by an early experiment in the USA involving the modification of pigs with the human growth hormone gene. The aim of this experiment was to produce leaner meat but the resulting animals were severely arthritic. Subsequent studies have circumvented this problem by the use of more sophisticated forms of gene construct.

3.17 In **Annex B** we highlight the strict controls that exist in the UK on animal experimentation and on the welfare of farm animals. Although no controls can prevent all unforeseen developments we believe that the UK legislation would be invoked at an early stage to end any experiment which raised welfare concerns. It seems to us that ethical concerns over genetic modification and animal welfare are not different in nature from those raised by modern breeding and farming methods generally. We do not therefore see a case for additional welfare controls specifically in relation to genetic modification programmes involving animals. Neither do we see a case for special labelling rules to deal with animal welfare issues in relation to genetically modified animals, beyond any systems devised to meet more general welfare concerns.

Transfer of Copy Genes of Animal Origin to Plants

3.18 This issue raises similar concern over copy genes from religiously banned animals as did transfers between animals. The positions taken by the various religious groups are the same. In addition, there is the issue of the attitude of vegetarians, and particularly vegans who avoid the consumption of all animal products. Representatives of vegetarian groups pointed out that there was considerable

diversity of dietary practice within vegetarianism. Those vegetarians who object to meat eating solely because of concern over animal husbandry and slaughter are unlikely to object to GM plants containing copy genes of animal origin. However, some individuals are likely to find the presence of even a single copy gene of animal origin in a plant species to be unacceptable. If the animal genes involved were "synthetic", this might be acceptable to some who would avoid such products if the animal genes were copy genes of animal origin.

3.19 We note in this respect that the chymosin *enzymes* produced by genetically modified organisms are accepted by the Vegetarian Society. These enzymes which are used in cheese production are produced by yeasts or bacteria modified to carry the bovine chymosin gene. They represent an alternative to the traditional source of the enzyme: rennet obtained from calves' stomachs. The enzyme is thus "calf-like" although it is now produced without any animal involvement. We understand, however, that not all vegetarians support this view and that the Society's endorsement of this product is under review.

Transfer of Copy Genes of Plant Origin to Other Organisms

3.20 This does not seem to have raised ethical concerns amongst any groups except the minority who object to the process absolutely. Although we did not specifically explore the point we believe the transfer of genes from micro-organisms to other organisms would be similarly widely acceptable from the ethical standpoint.

Transfer of Copy Genes of Non-food Animal Origin to Other Organisms

3.21 In the course of our discussions it was drawn to our attention that there are religious objections to eating certain flesh which go beyond the more usual taboos we described above. For example, Muslim dietary restrictions extend to the consumption of the flesh of any meat-eating animal, such as dogs or lions. Others might not wish to consume food containing genetic material from animals to which there is a particular human attachment (e.g. horses) or human revulsion (e.g. rats). We regard these latter attitudes as relating to matters of taste rather than ethics, and so outside the scope of our study. In any case, it seems most unlikely that there will be widespread use of genes from these animals in the foreseeable future, although we understand that the insertion of repellent *pheromone* genes from higher animals (e.g. mice or deer) into plants could be proposed for pest control. We believe such developments may need to be brought within the framework for responding to the concerns that affect the more obvious dietary restrictions, which we discuss in the next chapter.

Food Use of Unmodified Animals

3.22 We began this report with a brief description of the issue which led to our establishment. This concerned the fate of food animals used in genetic modification programmes when modification had proved unsuccessful. With current technology the frequency of successful modification of food animal embryos is low: typically around 1 per cent of animals born contain the gene, but only 0.1 per cent of animals express it. We have received few representations on this issue and conclude that there are no ethical objections to unmodified animals (which are by definition fundamentally no different from any others) entering the food chain, except for the minority which feel that there is an absolute "moral taint" arising from any form of participation in a programme of genetic modification. We note that other animals

used in experimental programmes are allowed into the food chain subject to the strict licensing arrangements described in **Annex B.** However, there is no provision for labelling such animals to allow consumers to choose whether to avoid their meat. We see no special reason for treating "unmodified" animals from genetic modification programmes any differently from other experimental animals. We note, however, that to demonstrate that an animal is "unmodified" (in the sense that none of its cells contain foreign genetic material) may actually cost more than its commercial value. It may therefore suit companies to treat all animals from a modification programme as potentially modified and hence subject to the arrangements that we propose in the next chapter.

Copy Genes of Human Origin in Animal Feed

3.23 We received few representations on this issue. Some of those who commented pointed to the need for respect for human dignity; others did not see it this way. It seems that attitudes will be determined by the view taken of the ethical status of copy genes of human origin in the same way that this determined attitudes to the consumption of copy genes of human origin in food.

The Controlling Factor

3.24 In summary, all the issues concerning the transfer of genetic material to a new species must involve a decision about what is the controlling ethical factor defining the new situation. The views of our respondents varied from the presence of a single gene (perhaps differing only in a few nucleotides from a "host" gene), to the view that it is the whole animal that counts (if it looks like a sheep it is a sheep). This latter view would tolerate substantial modifications without concern. Our recommendations have to take into account the existence of these conflicting assessments.

Attitudes to Foods and Medicines

3.25 We note that there is presently no requirement to label medicines as resulting from genetic modification or to record whether particular medicines have been produced from particular animals, unless such information was relevant in relation to safety. We asked those religious groups that exercised discrimination in the types of animals they would eat, what was their position in relation to corresponding medicines or transplants of animal organs. Virtually all faiths take the view that the preservation of human life is the first priority. Thus Jews will readily accept the transplant of an organ even if it originated from a pig, if it results in saving human life. Such practice is supported by their view that the human body can only be violated by oral intake and not by other methods of introduction, such as injections or surgery. Muslims take a stricter view and would regard any product derived from a pig (e.g. pig insulin) as unacceptable. However, if a Muslim doctor agrees that the product is the only way to sustain life, an exception can be made.

3.26 Against this general background, we had to consider whether there was a case for taking special steps to provide information to allow particular consumers to exercise choice in relation to the food they consume, when such steps are not taken in relation to medicines. It was put to us that the two situations are not equivalent. Medicines are taken when a threat to life or health is present and the benefits are judged by a professional adviser to outweigh the risks. This was not the same as consuming food, which was generally perceived as being a risk-free practice in which the choice of the individual should be preserved as far as possible. We accept this

distinction, and therefore do not regard the position on medicines as setting a precedent for food.

Synthetic Genes

3.27 Running through all the issues discussed above was the belief by some groups that the origin of the material determined its ethical status. We therefore put it to them that attitudes might be different if the introduced gene were manufactured in a test tube, rather than copied from the host organism, and thus could be viewed as entirely "synthetic". We received no clear response on this issue. However, to a greater or lesser extent, groups were prepared to acknowledge that this might affect the position that they took on a particular type of modification and could affect the attitude of at least some individuals within the communities involved. They all suggested that there was a need for greater education about the genetic modification process, and further discussion within their communities, before a definitive view could be offered. However, we saw sufficient indication of flexibility on this point to suggest that this issue might usefully be pursued and we discuss it further in the following chapter.

4. RESPONSES

General

4.1 It will be apparent from the foregoing discussion that there are no universally agreed conclusions which emerge from the submissions to our Committee. Some groups or individuals have wide-ranging ethical prohibitions and others have none. Our recommendations, therefore, must take account of the existing plurality of ethical views.

4.2 In considering particular genetic modifications, debate has centred on the presence of different types of genetic material. In most cases it is possible that the protein product of the foreign DNA would also be present, although the protein would not be present without the DNA. The attitudes we have explored and the recommendations we make therefore centre on the presence of foreign DNA, whether or not foreign protein is also present.

Transfer of Copy Genes of Human Origin to Other Organisms

4.3 It is clear that there is a quite widespread concern about the incorporation of copy genes of human origin into food organisms. Some groups regard this as ethically unacceptable; to some it is merely distasteful; whilst to others it is a matter of no particular concern. We see no grounds for seeking to prohibit the medical opportunities offered by the production of important pharmaceuticals in farm animals. We have considered, however, whether there is a case for banning the animals and their products from entry into the food chain.

4.4 It seems to us that the key factor in consideration of this issue is the view taken of the status of the human genetic material inserted into the farm animal. The consumption of significant quantities of human matter would be ethically objectionable to all, except perhaps in the most extreme circumstances. However, most of us in our everyday lives occasionally consume small amounts of human DNA. Such events are not regarded as a matter of any ethical consequence and we do not generally adopt special safeguards to avoid the possible ingestion of, say, tiny quantities of human skin. Any precautions that are taken, for instance in the preparation of food, are for reasons of hygiene rather than ethics. We are not, therefore, excessively scrupulous in avoiding the consumption of minute quantities of human DNA.

4.5 A more fundamental consideration, however, is the nature of the "human" material transferred in genetic modification. As explained in Chapter 2, because a number of steps are taken *in vitro* to purify and replicate the donor gene, for all practical purposes, **the inserted material is not "human", in the sense that it contains DNA derived directly from a human donor.** Furthermore, at present most genetic modifications involve the transfer of single genes although it is becoming possible to transfer clusters of genes associated with a particular function (e.g. the production of certain antibodies) or a series of single genes coding for a variety of functions (e.g. pest resistance and improved storage characteristics). However, **none of the modifications now in prospect would have multiple consequences so general and widespread that the essential *phenotype* of the recipient species would be altered.**

4.6 Finally we note that when food from an organism including DNA of human origin is eaten by human beings, the human DNA is broken down in the human alimentary tract and so loses all its genetic identity.

4.7 It is in the light of these considerations that the Committee has taken the position that a copy gene of human origin in another organism can be viewed differently from the same gene within an individual. **We support the view that the status of genetic material derives from its context in the whole organism. We do not, therefore, support a case on ethical grounds for an absolute prohibition of the food use of organisms containing copy genes of human origin.** However, we recognise that this view is not universally held and we believe means need to be found to enable those who object to exercise the choice to avoid such products.

4.8 The fact that we find the food use of organisms containing copy genes of human origin acceptable does not mean that we believe the incorporation of copy genes of human origin into food organisms should be undertaken without restriction. **It seems to us that there is a strong ethical case for certain medical developments involving transgenic organisms, and that it is acceptable that the farm animals or other food organisms so produced should be used as food rather than discarded needlessly.**

4.9 There may also be cases where the production of food itself may require the development of transgenic animals with copy genes of human origin. For instance, we understand that some initial research is in progress involving the modification of cattle to incorporate copy genes of human origin so that the milk they produce more closely resembles human milk. This would avoid the elaborate formulation of infant products and should benefit children's health.

4.10 However, **we would not support the uncontrolled use of copy genes of human origin for food production purposes, such as faster growth rates, when the same result might be achieved using copy genes of non-human origin.** As indicated earlier, there is often close homology between genes of different species and a suitable technical alternative is likely to be available. We believe that the ACNFP should consider expanding its guidelines* to require notification by those seeking clearance to market a novel food of why a copy gene of human origin, or other "ethically sensitive" copy gene, had been employed rather than an alternative.

Transfer of Copy Genes of Animal Origin to Other Animals or Plants

4.11 Amongst the other types of modification discussed in Chapter 3, two gave rise to special concerns. The first involved the transfer of copy genes of animal origin to other animals, where the major concern centred on genes from animals subject to dietary restrictions. The second involved the transfer of copy genes of animal origin to plants which, in addition to the issue of the religiously prohibited animal species, could be of concern to vegetarians. **These concerns are less widely held than those concerning copy genes of human origin but nevertheless we believe they are of sufficient scope and consequence that mechanisms should be provided to allow individuals to exercise a choice.**

Providing Choice

4.12 The fundamental requirement in relation to all the examples considered above is for individuals to be allowed to make an informed choice. The point repeatedly stressed to us was that religious groups, and consumers generally, want to be able to make up their own minds about what they eat. Almost all our

---

**Guidelines on the Assessment of Novel Foods and Processes*, HMSO, ISBN 0-11-321336-0.

respondents asked for labelling, viewing this as the only effective way of allowing them to exercise such choice. It was noticeable that even those responses which indicated that the particular group did not itself require labelling, argued in favour of labelling to allow others to make the choice that their ethical stance demanded. Since labelling is so fundamental to our review it is discussed in Chapter 5.

Copy Genes of Human Origin in Animal Feed

4.13 It follows from our conclusions in relation to copy genes of human origin in human food that we do not see a case on ethical grounds for prohibiting the use of organisms, such as yeast containing copy genes of human origin, which has been used in another process, from use as animal feed. It seems likely such organisms would only be developed for medical purposes.

Synthetic Genes

4.14 As previously indicated, a point that we have particularly explored is whether synthetic material (i.e. a DNA sequence synthesised *in vitro*) is free from ethical perplexities. Some, who would otherwise be opposed to the inclusion of particular genes, are prepared to concede that it is. Others believe that it might be, but that the public at large is not yet sufficiently familiar with the details of genetic modification to recognise a distinction. We believe that the ethical evaluation of this distinction should be pursued by encouraging its discussion within religious and other groups. We do not feel that at present there is sufficient certainty on attitudes to warrant making a distinction in the recommendations we make. However, in the longer term this might represent an acceptable means of introducing genes which would otherwise be objectionable.

5. LABELLING, INFORMATION AND EDUCATION

General

5.1 As noted in the previous chapter, almost all responses to our consultation from consumer and religious groups asked for some form of labelling as essential for ethically necessary, informed choice. We realise that there is a good deal of reluctance on the part of industry to accept labelling. We understand their concern that labelling raises many practical problems and that it is very likely to be viewed negatively, as it has been with food additives and food irradiation. We appreciate too that there will be considerable difficulty in enforcing any rules. Nevertheless, it seems to us that many of the concerns felt by the different groups, with their various prohibitions and doubts about the eating of certain foods which have involved genetic modification, can **only** be met by adequate labelling.

5.2 Some groups will insist on a very rigorous and extensive labelling approach. We believe this is neither necessary nor practical as a general policy. If such groups wish to pursue this, they will need to organise their own labelling systems (as the vegetarians have done with their "V" mark system, or the kosher rules for Jews). For instance, we do not believe that enforced labelling should be required to meet the concerns of certain animal welfare groups who may wish to avoid all foods involving genetic modification. Such groups will need to seek details from retailers and manufacturers and take their own steps to avoid particular products if they are not satisfied.

5.3 We are aware that the FAC has been considering for some time the broader issue of the labelling of genetically modified foods. The Committee produced draft guidelines for comment in 1991 and has recently sent out a second consultation paper on this issue. We are considering only one aspect of the issues involved and we are conscious of the fact that our approach will have to fit within any wider system that the FAC may propose. We have, therefore, proposed a few key principles which the FAC will wish to take into consideration in its broader study, rather than making detailed proposals in this area.

5.4 It follows from the "dilution effect" described in Chapter 2 and our conclusion that copy genes of human or animal origin do not merit a special ethical status, that we would not, on our own account, see a need for such genes to be identified in food. Nevertheless, it is quite clear that our perception is not shared by many of the groups from whom we received evidence. We believe, therefore that **the first and most important requirement is for a system of labelling which permits informed choice in relation to the presence of ethically sensitive transgenes in food.** We believe this implies that labelling should apply to copy genes of human origin, copy genes originating from cattle and pigs introduced into other farm animals, and copy genes of animal origin introduced into plants or micro-organisms. This list should be kept under review and consideration given to its extension, particularly in relation to the issues described in paragraph 3.21.

5.5 We have considered whether labelling should take the form of a positive (presence) or negative (absence) system. The former would involve the declaration of the presence and nature of foreign genetic material, whereas the latter would involve a declaration of the absence of any types of foreign DNA. A major practical distinction between these approaches is that presence labelling could be made a legal requirement, whereas absence labelling would be likely to be feasible only if organised by special interest groups to meet their own concerns. This is because it needs to be

recognised that procedures for determining presence or absence can only practically be defined within the limits of "best endeavours" (paragraph 5.6). We therefore believe that consideration should be given to a positive system of labelling.

5.6 The second concerns the inclusion of a *de minimis* principle (i.e. no undue concern about very small matters). It seems to us that it will be quite unrealistic to label every last element of modified food in every product in which it may be incorporated. **We therefore believe that a *de minimis* principle should apply.** This is not inconsistent with the approach found in major ethical systems. All such systems normally incorporate a principle of "best endeavours" in the knowledge that absolutes are impossible to observe. We therefore see no ethical reason why such a principle should not be applied in the case of genetic modification and dietary choice. It is not possible to express in precise quantitative terms when such a principle should operate, since the decision has to take into account the practicalities of each individual case. We do not, however, think that it will prove difficult to make ethically responsible judgements of this kind.

5.7 The third concerns the need to label "derived products of specific, non-genetic nature" (i.e. products which cannot be distinguished chemically from the same product obtained from an unmodified organism). A number of foods will be the products of genetically modified organisms (GMO), rather than contain or consist of the GMOs themselves. We would see no need to label a highly purified product, such as sugar produced from a modified sugar beet (even if the beet plant contained copy genes of human origin), because no genetic material would be consumed. However, if the beet itself were consumed we believe it should be labelled. We appreciate that there are a number of intermediate possibilities between these two situations (e.g. consumption of processed beet fibre) but we believe it will be for the FAC to suggest detailed rules on how these might be dealt with. **The principle that we wish to establish is that the major ethical concerns expressed to us relate to the consumption of the transgene rather than to the genetic composition of the source from which the food product was obtained.**

5.8 Furthermore, we observed in Chapter 2 that certain processing techniques will degrade or destroy the DNA present in a food. It follows from the position we take on "derived products of specific, non-genetic nature" materials that we believe if destruction is complete then the case for labelling falls.

The European Community Dimension

5.9 We recognise that ultimately rules on food labelling are laid down at Community level within the EC. Any proposals we make will need to be included within the wider scheme being considered by the FAC. UK Ministers will then need to take a view and negotiate provisions in Brussels with other Member States. This process is bound to involve some give and take. Nevertheless, the ethical concerns expressed to us seem likely to be shared by the citizens of other Member States.

Other Forms of Public Information

5.10 We have considered whether there are alternatives to labelling to allow for choice. The nature of the introduced gene and of the modified organism are pertinent information, but there will be practical constraints on entering this information on a food label, particularly if it relates to only one ingredient in a complex product. We have, therefore, looked briefly at whether there are alternatives to labelling, particu-

larly for providing more detailed information than can conveniently be displayed on the food label.

5.11 There are already a number of central databases containing information on food constituents. With the rapid advances in information technology it may become possible to provide additional information on GM foods by this or other means. To the extent that such developments occur we would see them as a welcome adjunct to labelling. We do not see a need for all the details of a genetic modification to be included on a food label if supplementary information is available elsewhere.

Public Education

5.12 In the course of our deliberations a number of groups drew attention to a wider need for public information and education about the use of genetic modification, particularly in relation to food production. We are aware that MAFF and the Food Safety Advisory Centre have produced consumer leaflets on this matter and that MAFF is contributing financially to a substantial programme by the British Nutrition Foundation involving the development of "schools packs" which will include educational material on genetic modification. In Chapter 8 we make recommendations aimed at encouraging a reconsideration of attitudes in the light of the "dilution effect", cDNA and the possible use of synthetic genes. Beyond this, we make no specific recommendations in this area but would add our general support to the various educational initiatives. Genetic modification is clearly a powerful technology which offers major scientific and economic opportunities. But it will only flourish if its products are acceptable to consumers. A better general understanding of what is involved can only help that process.

6. GENETIC MODIFICATION AND THE FOOD CHAIN: FUTURE DEVELOPMENTS

6.1 Genetic modification offers opportunities both to developing and developed countries. In the former, agricultural productivity will be the key aim. In the latter, developments are likely to be directed towards increasing agricultural efficiency and improving the quality and safety of food. A further aim will be to reduce the input of chemicals into animal and food production. Although genetic modification has been carried out successfully in food micro-organisms, plants and animals, the commercial application of the technology has yet to become widespread and few products have yet been authorised to enter the human food chain in any country.

6.2 Some of the first applications of the new biotechnologies occurred in the food sector. This was partly because of familiarity with traditional fermentation and enzyme applications which had long been based on the principles of biotechnology. The genetic modification of food micro-organisms has already provided alternative sources of enzymes – such as chymosin for cheese making, which is traditionally obtained from calves' stomachs – and improved strains of yeast for use in food manufacture. In the future, advances are expected both in enzyme production and in the development of micro-organisms, notably bacteria, to improve the flavour, nutritional quality and preservation of food.

6.3 In plants, as in animals, genetic modification is expected to raise productivity and improve product quality. Crop species from most of the major families of plants have been genetically modified and current research involves the introduction of genes controlling characters important in agronomy (disease and pest resistance and tolerance to cold, drought, salinity and heavy metals), food processing (improved wheat qualities for bread making) and human nutrition (increased protein content in cereals). Much of the research on plants is still experimental but genetically modified tomatoes with a longer shelf life and better taste characteristics are likely to be available to consumers soon.

6.4 In the animal sector, improved quality and productivity are research objectives using selection by advanced reproductive technologies or by genetic modification. Examples are the introduction of genes that code for valuable proteins (resulting in the improvement of milk products to meet the specialised needs of new-born infants and adults or the production of pharmaceuticals in milk) and the modification of livestock to ensure the maintenance of growth and yield when fed a lower-quality high-fibre diet. The introduction of genetic resistance to disease remains a further objective in animals including fish.

6.5 Apart from the genetic modification of micro-organisms, plants and animals specifically for use in the food sector, those developed for other purposes are likely to impinge on the food chain. These include genetically modified animals and plants used in the production of pharmaceuticals or of raw materials for industry. The food chain may be further affected by changes in the availability of certain plant products, for example, the present ecogeographical limits of crops such as maize and soya beans may be extended northwards.

6.6 A striking feature common to most sectors is the widespread and promising use of genetic modification for the improvement of health, particularly through the development of new diagnostics important for healthcare in humans (e.g. identification of food contamination), animals and plants (e.g. disease diagnostics and prevention).

6.7 These potential developments do not enlarge the main areas of ethical concern identified in our study involving:

— copy genes of human origin in food animals and plants;

— certain copy genes of animal origin in other food animals;

— copy genes of animal origin in plants.

6.8 Amongst the potential areas of research involving genetic modification we do not anticipate many commercial developments that will involve these sorts of modifications in the next five years. The main use of copy genes of human origin is likely to be in the production of pharmaceuticals in plants and food animals. Animal-to-animal copy gene transfers are likely to be more common because of the wide range of potential applications. However, such transfers are technically more difficult and developments are likely to be fewer and less immediate than those involving micro-organisms and plants.

6.9 A small number of coding sequences of animal origin have been transferred to plants and the products expressed. These include the sequences for *casein* and other high-*lysine* proteins, and antibodies. Coding sequences, rather than the complete genes, are being used because (as noted in **Annex H**) the sequence as found in the genome contains sequences *(introns)* which are not transcribed into messenger RNA. Thus the gene introduced into the plant is not how it appears in the animal. The gene product is, however, the same.

6.10 In short, therefore, we believe modifications raising particular ethical concerns will be uncommon when viewed against all the uses of genetic modification in relation to the food chain.

7. CONTINUED MONITORING

7.1 In 1992, our Chairman (Reverend Dr J Polkinghorne) was appointed to the ACNFP to provide an additional dimension to the Committee's existing scientific expertise. The role of the Committee's ethicist is to identify any points under discussion which might raise ethical concerns requiring further investigation. In such instances it is envisaged that the need for an *ad hoc* study group, such as our own, might be considered.

7.2 This report proposes that in one important respect the ethical dimension to the ACNFP should be extended. It is proposed that an additional check should be incorporated into the ACNFP guidelines to discourage the unnecessary use of ethically sensitive copy genes in novel foods.

7.3 During the consultation exercise several organisations expressed the opinion that a standing committee should be established to consider ethical issues raised by genetic modification in relation to food. Such a body would draw together information as issues arose and make recommendations to Government or to other bodies such as the ACNFP.

7.4 Given the arrangements summarised above we do not believe that the case for such a committee has been made out at this stage. A mechanism is already in place to address ethical matters and fuller *ad hoc* studies can be set up if the need arises. Nevertheless, we do accept that the position needs to be kept under review in the light of developments.

8. SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

8.1 We see no overriding ethical objection which would require an absolute prohibition of the use of organisms containing copy genes of human origin as food. We *recommend* that organisms containing copy genes of human origin may be used in the food chain subject to the necessary safety assessment. However, we *recommend* that the ACNFP guidelines be expanded to discourage the use of all ethically sensitive genes in food organisms where alternatives are available (paragraphs 4.10 and 7.2).

8.2 We see no ethical objection to the use, as food, of animals from genetic modification programmes, which have not been modified. We *recommend* that organisms from GM programmes which can be clearly demonstrated not to have been modified should be allowed into the food chain without restriction beyond those that already apply to other types of animals from experimental programmes (paragraphs 3.17 and 3.22).

8.3 We recognise that many groups or individuals within the population object on ethical grounds to the consumption of organisms containing copy genes of human origin. We therefore *recommend* that food products containing such organisms should be labelled accordingly to allow consumers to exercise choice (paragraph 4.7).

8.4 We recognise that some groups or individuals within the population object on ethical grounds to the consumption of organisms containing copy genes from animals which are the subject of dietary restrictions for their religion. We recognise that similar ethical objections would be held by certain vegetarians in relation to any copy gene of animal origin incorporated in a plant. We *recommend* that appropriate food products should be labelled accordingly to allow these groups to make an informed choice (paragraphs 5.1 and 5.4).

8.5 We understand that detailed proposals on the labelling of genetically modified foods are being elaborated by the FAC. We have therefore not made specific recommendations which might intrude in their wider field of work. Our deliberations have, however, identified two further principles which we believe merit consideration. The first is that a *de minimis* principle should apply in recognition of the practicalities of the situation. The second is that "derived products of specific, non-genetic nature" products need not be labelled. We *recommend* that the FAC should take these two concepts into consideration in formulating its final guidelines (paragraphs 5.6 and 5.7).

8.6 We recognise that labelling may not be able to provide all the information consumers might wish to have. We therefore *recommend* that industry and Government should explore the prospects for additional means of providing information to the public on the modifications applied to particular foods (paragraphs 5.11 and 5.12).

8.7 We note that a number of respondents wish to see the establishment of a standing ethics committee. However, we believe the case for such an arrangement has not been established. We *recommend* that existing arrangements involving the ACNFP should continue but that they should be kept under review (paragraph 7.4).

8.8 We note that the "dilution effect" or the use of cDNA results in transgenes losing their original "status" in the sense that they are manufactured in *in vitro* systems rather than derived direct from a donor organism. This fact is not generally appreciated outside the scientific community. We *recommend* that this issue is

further debated, particularly within the religious communities, since it might lead to changes in the attitudes recorded in our report (paragraphs 2.8 and 5.12).

8.9 We note that a number of the ethical objections surrounding the use of introduced genes might be removed if the genes were entirely "synthetic". We *recommend* that this issue is further debated, particularly within the religious communities to see if this might offer a way forward which would not impede scientific advance but would remain consistent with religious beliefs (paragraphs 4.14 and 5.12).

EXISTING SAFETY CONTROLS ON GENETIC MODIFICATION AND GENETICALLY MODIFIED FOODS

There are a number of controls placed on the use of genetic modification in order to safeguard human health and the environment. The Genetically Modified Organisms (Contained Use) Regulations 1992 and 1993 control all aspects of laboratory work or other "contained uses" involving genetic modification and require that a risk assessment be carried out beforehand. The Genetically Modified Organisms (Deliberate Release) Regulations 1992 and 1993 require anyone who intends to release GMOs into the environment first to obtain a consent from the Department of the Environment. All proposals to sell products consisting of or containing GMOs must similarly be covered by a consent. The food use of products derived from genetic modification programmes is currently controlled under voluntary arrangements administered by MAFF and the Department of Health. These arrangements are due to be superseded by statutory controls introduced under an EC Regulation on Novel Foods currently under discussion in Brussels. The Government receives expert advice in relation to these three areas from the following independent advisory committees:

1. **Advisory Committee on Genetic Modification (ACGM):** ACGM advises the Health and Safety Commission, the Health and Safety Executive and the Government on aspects of work activities involving genetic modification.

2. **Advisory Committee on Releases to the Environment (ACRE):** ACRE advises the Government on all aspects of human and environmental health and safety of the introduction of GMOs into the British environment.

These two bodies are often involved in considering certain aspects of a particular genetically modified organism at the research or developmental stage prior to its submission to the ACNFP for clearance for food use.

3. **Advisory Committee on Novel Foods and Processes (ACNFP):** The ACNFP is comprised of independent, scientific experts drawn from universities, research establishments, industry and the consumerist sectors. This Committee concentrates on the safety implications of introducing novel foods (including those produced by genetic modification) to consumers. Its remit is:

> "to advise Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Social Services and Agriculture for Northern Ireland on any matters relating to the irradiation of food or to the manufacture of novel foods or foods produced by novel processes having regard where appropriate to the views of relevant expert bodies."

ANIMAL WELFARE CONTROLS

1. Special legislative controls exist on animal experimentation in addition to more general controls on the rearing and keeping of animals. In both these areas the Government is advised by independent committees and legislative controls are backed by guidelines or codes of practice.

Animal Experimentation

2. The Animals (Scientific Procedures) Act 1986 regulates any experimental or scientific procedure which may have the effect of causing an animal pain, suffering, distress or lasting harm. It ensures that every proposal to use live animals is subject to a rigorous assessment of its scientific justification, the quality of its design and the balance between its potential benefit and the likely effect on the animals used. To ensure that the outcome of any modification can be regarded as harmless, observations of the whole life span of at least two generations of offspring must be carried out. The Act is enforced by the Animals (Scientific Procedures) Inspectorate within the Home Office and experiments are controlled through a system of licensing.

3. The Government is advised on animal experimentation matters by the Animal Procedures Committee, an independent body established under the Act. In 1990 the Committee concluded that the present controls were adequate to safeguard transgenic animals. The production of genetically modified animals comes under the control of the Act because of the nature of the procedures involved and the potential for harm to offspring. The balance between the relative cost to the animals and the expected benefit from experimentation must be weighed before any work of this sort is authorised under the Act.

4. As noted above, the outcome of experimentation has to be observed over the life span of at least two generations of animals before they are considered for discharge from the control of the Act. Any transgenic animal exhibiting welfare problems would remain subject to the controls of the 1986 Act. Animals discharged from the Act remain subject to the general controls described below.

General Controls

5. General controls are included in the Protection of Animals Act 1911 and the Agricultural (Miscellaneous Provisions) Act 1968. The former Act makes it an offence for any person to cause unnecessary suffering to any domestic or captive animals; the latter makes it an offence for any person to cause unnecessary pain or unnecessary distress to any livestock situated on agricultural land. The Acts are enforced by various bodies including local authorities and the State Veterinary Service within MAFF.

6. The Government is advised on farm animal welfare issues by the Farm Animal Welfare Council (FAWC). This is an independent advisory body appointed by the Government in 1979. Its terms of reference are:

> "To keep under review the welfare of farm animals on agricultural land, at markets, in transit and at the place of slaughter, and to advise the Minister of

Agriculture, Fisheries and Food and the Secretaries of State for Scotland and Wales of any legislative or other changes that may be necessary."

7. The Council believes that an animal's welfare can be considered in terms of the following five freedoms: freedom from hunger and thirst; freedom from discomfort; freedom from pain, injury or disease; freedom to express normal behaviour; and freedom from fear and distress. Numerous recommendations made by the Council have been implemented in the form of legislation and welfare codes.

CONSULTATION LETTER

To all organisations on the attached list

25 September 1992

Dear Consultee

GENETIC MODIFICATION PROGRAMMES AND FOOD USE

Ministers have recently commissioned an ad hoc study of the ethical issues that may arise from the potential consumption of genetically modified organisms (GMOs) or their products and related issues. Details of the study group and their remit are given in the announcement at *appendix A* to this paper. It should be emphasised that the scope of the study does not extend to the ethics of genetic modification (GM) per se but is limited to the food use of organisms from GM programmes. Some basic information on genetic modification is provided in the enclosed fact sheets.

This study in part arises from a report by the Advisory Committee on Novel Foods and Processes (ACNFP) (see *appendix B*). The Committee had considered the safety of using as food, farm animals produced by GM research programmes aimed at the transfer of human genes to such animals in order to make possible the production of a range of pharmaceutical products. The resultant 'transgenic' animals would produce medically valuable, nature identical human blood proteins in their milk. However, the proposals considered by the ACNFP concerned only those animals in which the intended insertion of new genetic material had not occurred. The Committee concluded that for certain categories of animals produced by these programmes it was possible to determine unequivocally that the intended modification had not been achieved and that, therefore, the animals were perfectly normal and so raised no food safety concerns.

However, in framing their advice on safety the ACNFP also highlighted the possible ethical issues to arise from the marketing of animals from transgenic modification programmes as food. In commissioning this study Ministers have sought to obtain considered and informed advice on this and other related ethical issues which may arise, as outlined below.

There appear to be four actual or potential types of development which could give rise to ethical concerns in relation to the consumption of food. These are summarised below:

— the transfer of human genes to food animals (examples include the sheep in which a human blood clotting factor gene had been incorporated; both modified animals and those in which incorporation of the foreign DNA had not occurred could potentially be used for food);

— the transfer of genes from animals whose flesh is forbidden for food to certain religious groups to animals which they normally eat (e.g. pig for Muslims and Jews, or cattle for Hindus; in the United States, cattle have been modified to carry the porcine growth hormone);

— the introduction of animal genes into food crops which may be of particular concern to vegan vegetarians;

— the use, as animal feed, of organisms containing human genes (e.g. yeast can be modified to produce human proteins of pharmaceutical value; consideration might be given to disposing of the spent yeast as animal feed).

At present none of the products referred to above is entering the human food or animal feed chains but it is the ethical concerns that could arise from such a practice that this study aims to address.

Initially the study team will attempt to assess likely future developments in this area and any information that you can provide on the nature of developments in the pipeline and their likely timescale would be very welcome. Additionally views are particularly invited on the ethnical concerns that could arise from the type of developments described above and on the following points:

— whether there should be controls on the food use of any particular type of product and if so what form such controls should take and which products should be covered;

— whether concern might be met through labelling or other forms of information to consumers or by some other means.

The group would be most interested to have your views by *20 November.* These should be sent to *Mr Tim Davis, Study Group on Genetic Modification Programmes and Food Use, Ministry of Agriculture, Fisheries and Food, R425, Ergon House, c/o Nobel House, 17 Smith Square, London SW1P 3JR (FAX 071 238 6382).*

In order to help inform debate on the issues raised by this consultation document, MAFF intends to make publicly available, at the end of the consultation period, copies of the responses received. The main Departmental Library at 3 Whitehall Place, London SW1 (tel: 071 270 8419) will supply copies on request to personal callers or telephone inquirers who may produce further copies. It will be assumed, therefore, that your response can be made publicly available in this way, unless you indicate that you wish all or part of your response to be excluded from this arrangement.

If you have no objection to your response being made available for public examination in the way described above, would you please supply an additional copy of your response to this consultation document.

Yours sincerely

T J Davis
Secretary to the Study Group

Consultation List – Ad Hoc Study

AFRC Institute of Grassland and Environmental Research
A G Barr and Co Ltd
Agricultural and Food Research Council (Bristol)
Agricultural and Food Research Council (Reading)
Agricultural and Food Research Council (Swindon)
Anjuman-E-Gujarate Muslim Soc
ASDA Stores Ltd
Assoc of British Pharmaceutical Industry
Assoc of District Councils
Assoc of Local Authorities (N.I.)
Assoc of Metropolitan Authorities
Assoc of Muslim Scholars of GB
Assoc of Port Health Authorities
Assoc of United Synagogue Ladies Guilds
Bahá'í Community of the UK
Bhartiya Vidya Bhakan
Board of Deputies of British Jews
Board of Shechita
Board of Social Responsibility of the Church of Scotland
Booker Services Ltd
BRF International (Brewings) Research Inst
British Council of Churches
British Dietetic Assoc
British Industrial Biological Research Assoc
British Medical Assoc (Edinburgh)
British Medical Assoc (London)
British Meat Manufacturers
British Nutrition Foundation
British Retail Consortium
British Society of Plant Breeders
British Starch Industries Assoc
British Union Conference of Seventh-Day Adventists
British Veterinary Assoc
Buddhist Meditation Centre
Buddhist Society
Campden Food and Drink RA
Cardinal Cahal Daly
Catholic Bishops Joint Committee on Bioethical Issues
Centre for Agricultural Strategy
Chief Rabbi
Church of Ireland Diocesan
College of Physicians
Consumers Association
Consumers in the EC Group
Cooperative Stores Ltd
Cooperative Women's Guild
Council for Science & Society
Council of Mosques – UK
Council of Rabbinical Authority of the Independent Orthodox
Council of Welsh Districts
Cranfield Biotechnology Centre
Digest: Food Policy and Legislation
Eastern Health and Social Services Board

Ethicon Ltd
European Islamic Mission
Evangelical Movement of Wales
Express Foods Group Ltd
Farmers Union for Wales
Federation of Synagogues
Food Commission
Food & Drink Federation
Food Safety Advisory Centre
Free Church of Scotland
Free Presbyterian Church of England
Gateway Food Markets Ltd
General Consumer Council for N.I.
General Synod of the Church of England
Genetics Forum
Gist Brocades NV
Good Housekeeping Institute
Green Alliance
Guild of Food Writers
Hindu Centre London
Horticulture Research Inst
Hotel Catering and Institutional Admin
Iceland Frozen Foods Plc
Imperial Chemical Industries Plc
Inst of Biology
Inst of Environmental Health Officers
Inst of Food Science & Royal Technology (UK) (London)
Inst of Food Science & Technology (Edinburgh)
Inst of Food Technologists
Inst of Trading Standards Admin (Wellington)
Inst of Trading Standards (Nottingham)
International Food Information Service
International Supreme Council
Islam and Mosques Council UK
Islamic Circle Organisation
Islamic Cultural Centre
Islamic Education Trust
Islamic Foundation
Islamic Medical Assoc
Islamic Sharia Council
Jewish Communities in GB
J Sainsbury Plc
Jurgen Wenzel
Karma Kagyu Buddhist Centre
Leatherhead Food Research Assoc
Livestock Marketing Commission N.I. Ltd
Marks & Spencer Plc
Marks & Spencer Plc (Economic Information Dept)
Meat and Livestock Commission
Methodist Church (Belfast)
Methodist Church Division of Social Responsibility
Milk Marketing Board (N.10)
Muslim Concern UK
Nat Assoc of Local Govt Officials
National Assoc of Women's Clubs

National Citizens Advice Bureaux Council
National Consumer Council
Nat Council of Women GB
National Farmers Union (London)
National Farmers Union (Swansea)
National Farmers Union of Scotland
National Fed of Consumer Groups
National Fed of Meat Traders Assoc
National Fed of Women's Institutes
National Food Alliance
National Housewives' Assoc
National Union of Townswomen's Guilds
N.I. Agricultural Producers Associations (NIAPA)
N.I. Dairy Trade Federation
N.I. Egg Merchants Association
N.I. Federation of Meat Traders
N.I. Grain Trade Association (NIGTA)
N.I. Master Butchers Association
N.I. Meat Exporters Association
N.I. Poultry Federation
Office of the Chief Rabbi
Pandariman Trust
Parents For Safe Food
Pigs Marketing Board (N.I.)
Potato Marketing Board
Potato Processors Federation
Presbyterian Church General Secretary (Belfast)
Presbyterian Church of Wales
President Union of Orthodox Hebrew Congregations of GB and the Commonwealth
Procter & Gamble Ltd
Public Health Laboratory Service Board
Rabbinical Authority of the Union of Orthodox Hebrew Congregations
Radha Krishna Temple
Representative Body of the Church in Wales
Research Engineering Ltd
Rowett Research Institute
Royal Society for Health
Royal Victoria Hospital
Safeway Foodstores Ltd
SAGB
Scottish Agricultural College
Scottish Association of Meat Wholesalers
Scottish Consumer Council
Scottish Crop Research Institute
Society for the Reformation of Muslims in the UK
Soil Association Ltd
St Ivel Technical Centre
Surate Muslim Khalifa Society
Tesco Stores Ltd
Townswomen's Guild
Trades Union Congress
UK Action Committee for Islamic Affairs
UK Assoc of Frozen Food Producers
UK Assoc of Mans of Bakers Yeast
UK Council for Food Science and Technology

UK Fed of Business and Professional Women
UK Fed of Home Economists
Ulster Curers' Association
Ulster Farmers Union
Unilever Research
Union of Muslim Organisations of UK and Eire
United Kingdom Islamic Mission (London)
United Kingdom Islamic Mission (Oldham)
University of Nottingham (School of Agriculture & Food Sciences)
Vegetarian Society
Waitrose Ltd
Welsh Consumer Council
Wholesale Grocers Assoc of Scotland
Women's Farming Union
Women's National Commission

ORGANISATIONS SUBMITTING WRITTEN EVIDENCE

1. Agriculture and Food Research Council (AFRC)
2. Association of the British Pharmaceutical Industry (ABPI)
3. Association of District Councils
4. Association of Metropolitan Authorities (AMA)
5. Bahá'í Community of the United Kingdom
6. Biobridge
7. Bioindustry Association (BIA)
8. Board of Mission
9. British Medical Association (BMA)
10. British Nutrition Foundation (BNF)
11. British Retail Consortium
12. British Society of Plant Breeders Ltd
13. British Union for the Abolition of Vivisection (BUAV)
14. Buddhist Society
15. Compassion in World Farming (CIWF)
16. Confederation of British Industry (CBI)
17. Consumers Association
18. Consumers in the European Community Group (CECG)
19. Cooperative Union Ltd (COOP)
20. Council of Churches for Britain and Ireland
21. Council of Reform and Liberal Rabbis
22. Council of Welsh Districts
23. Earthkind
24. Food Commission
25. Food and Drink Federation (FDF)
26. Free Church of Scotland
27. General Consumer Council for Northern Ireland
28. Genetics Forum
29. Hindu Cultural Society (verbal response)
30. ICI Seeds
31. Institute of Biology
32. Institute of Food Research (IFR)
33. Institute of Trading Standards Administration (ITSA)
34. Institution of Environmental Health Officers (IEHO)
35. International Society for Krishna Consciousness
36. Islamic Medical Association
37. Jewish Reform Synagogues (Dr Julian Kinderlerer)
38. Knock Methodist Church
39. Laboratory of the Government Chemist (LGC)
40. Meat and Livestock Commission (MLC)
41. Methodist Church
42. National Consumer Council (NCC)
43. National Food Alliance
44. Office of the Chief Rabbi
45. Pharmaceutical Proteins Limited
46. Presbyterian Church in Ireland
47. Ramakrishna Vedanta Centre
48. Scottish Society for the Prevention of Cruelty to Animals
49. Seventh-Day Adventist Church

50. Sikh Forum
51. Union of Muslim Organisations of UK & Eire
52. Universities Federation for Animal Welfare (UFAW)
53. Vegetarian Economy and Green Alliance (VEGA)
54. Vegetarian Society
55. Vishwa Hindu Parishad (UK)
56. Women's National Commission

ORGANISATIONS WHO GAVE ORAL EVIDENCE

1. Compassion in World Farming
2. Islamic Medical Association/Union of Muslim Organisations
3. National Consumer Council
4. National Food Alliance
5. Office of the Chief Rabbi
6. The Sikh Forum
7. The Vegetarian Society

Representatives from the Vishwa Hindu Parishad were also invited to give oral evidence but were unable to attend.

THE FATE OF THE TRANSGENE

Uptake of DNA by Cells in Tissue Culture

The following paragraph describes how foreign DNA is deliberately introduced into mammalian cells in culture:

In a typical experiment, tissue culture cells are *transformed in vitro* by *plasmid* DNA in the following way. The cells are cultured such that they are dividing at their optimum rate *in vitro.* The cells are prepared for transformation in a three-step protocol: (i) the cells are fed with fresh growth medium shortly before transformation; (ii) the DNA is mixed with calcium chloride and added dropwise to a buffered salt solution to produce a DNA-calcium phosphate precipitate; the pH of this mixture must be adjusted to 7.1 (± 0.05) pH units; (iii) the mixture is applied to the cells and left for 16 hours. The cells are then washed three times with fresh growth medium and cultured for several weeks to derive colonies. Using plasmid DNA, the "typical" frequency of transformation is about 200 colonies/5 x 10^6 cells, or about 1 in 10^4. Thus under these "ideal" conditions, only about 1 in 10,000 of the carefully cultured cells takes up and expresses the plasmid DNA.

NEGLIGIBLE CHANCE OF INCORPORATING ORIGINAL HOST DNA IN A GENETICALLY MODIFIED PLANT OR ANIMAL

1. Each DNA molecule consists of two strands. During replication, the strands separate and a daughter strand is synthesised on each to form two DNA molecules. Both DNA molecules are made up of one original strand and one daughter strand. When the process is repeated, a new strand is synthesised on each original strand and each daughter strand to form four DNA molecules: two that consist of an original strand and a new strand and two that consist of a daughter strand and a new strand. This process is repeated many times – with every round of replication, a new strand of DNA is synthesised on each existing strand. However, there are still only two original strands present and these each form one half of a DNA molecule.

2. If the original DNA molecule is a gene sequence from a human that has been inserted into the bacterium *Escherichia coli,* after several rounds of replication the two original human strands will still be present but there will be many strands of identical DNA that are derived wholly from *E.coli* precursors – for example, after ten rounds of replication, 1022 new strands will have been formed.

3. This process of replication of a desired gene sequence is gene manipulation or gene cloning. It provides the pure genetic material which is essential for genetic modification experiments. At each step, a single DNA molecule is isolated from hundreds of thousands of sister copies and is used as the progenitor for the next round of manipulation. The consequence of this is that there is combinatorial dilution of the original sequence.

4. This "dilution" of the original host DNA can be seen by considering the steps involved in introducing a human gene into a new host organism:

(a) A human DNA molecule, which contains many gene sequences, is isolated and cut, using enzymes, into several fragments. These fragments are introduced into the DNA molecules of vector organisms (usually bacterial viruses) that replicate in a host organism (usually a bacterium, e.g. *E.coli*). The vector organisms are now described as "recombinant" as they contain human DNA sequences as part of their own DNA molecules. They now replicate in the host organism to make a "primary library". For each fragment of human DNA, there is an amplification of about 10^5 in the form of identical, recombinant virus particles, all of which carry copies of the particular fragment. The original fragment of the human DNA will still be present, as separate strands, in two of the recombinant virus particles, but diluted in a ratio of one in 10^5.

(b) The primary library is screened to identify the human gene sequence which is of interest. Once the sequence has been identified, a single recombinant virus particle (clone) in which it is found is amplified – allowed to replicate – to form a pure population of identical, recombinant virus particles containing the human gene. The amplification of the human gene sequence is about 10^5-fold, resulting in a further dilution factor of one in 10^5.

(c) This process of screening and amplification is repeated to ensure that the human gene sequence is free from any contaminating sequences. Again, amplification results in a dilution of one in 10^5 of the selected material.

(d) The selected recombinant virus is grown as a bulk preparation for manipulation, an amplification of 10^{10}-fold, or a further dilution of one in 10^{10} of the selected material.

(e) The human gene sequence is isolated from the recombinant virus and inserted into a different, more useful, vector called a plasmid. Plasmids are circular, extra-chromosomal DNA molecules. Like the virus vectors, the plasmids that are used grow in *E.coli.*

(f) To allow identification and selection of recombinant plasmids which contain the human gene sequence, the plasmids are grown in *E.coli.* This represents a dilution of about one in 10^4.

(g) A single recombinant plasmid is selected and grown as a bulk preparation. This is an amplification of 10^{11}-fold giving a dilution factor of one in 10^{11}.

(h) The human gene sequence is isolated, joined to the necessary control and selection sequences for expression in the final host and returned to a plasmid which is grown in *E.coli.* This results in a dilution factor of one in 10^4.

(i) A single recombinant plasmid containing the human gene sequence and the control sequences is selected and grown in bulk. This is an amplification of 10^{11}-fold or a dilution factor of one in 10^{11} . This recombinant plasmid preparation can be used to introduce the human gene into its new host.

5. The overall dilution of the original genetic material of human origin is:

$$10^5 \times 10^5 \times 10^5 \times 10^{10} \times 10^4 \times 10^{11} \times 10^4 \times 10^{11} = 10^{55}$$

At each stage a single molecule of DNA is selected. The chance of the original material of human origin figuring in the final modified organism is clearly vanishingly small.

COMPLEMENTARY DNA (cDNA)

1. The use of a cDNA library for gene cloning removes any possibility that the original human or animal DNA can be present in a genetically modified organism. cDNA is synthesised using mRNA as a template, which means that the original DNA is not involved in the cloning procedure.

2. A partially purified preparation of mRNA (often containing the mRNA from a number of genes) is isolated from a human, animal or plant cell and using a *reverse transcriptase* enzyme, strands of DNA complementary to the mRNA are synthesised. Hybrids of mRNA-DNA form, each consisting of one strand of mRNA paired with one strand of newly formed, complementary DNA.

3. The mRNA-DNA hybrids are treated sequentially with several different enzymes. The mRNA is destroyed and strands of DNA which have the same coding sequences as the mRNA are synthesised. This DNA is complementary to the DNA in the original mRNA-DNA hybrid. The two strands of DNA pair to form double-stranded cDNA.

4. The cDNA is prepared for cloning and is inserted into the DNA of a suitable vector organism (usually a bacterial virus) to make a cDNA library. A cDNA library is amplified by allowing the "recombinant" vector, which contains both the cDNA and its own DNA molecule, to replicate in a host organism (usually a bacterium such as *E.coli*).

5. The procedures described in **Annex G,** paragraph 4(b)–(i) are used to screen for and amplify the gene of interest present in the cDNA, and to transfer this gene into the new host organism.

6. cDNA is useful to genetic engineers as it does not contain introns – gene sequences that do not code for proteins. The mRNA is derived only from active gene sequences (exons) which code for proteins, and when it is used as a template for cDNA only the active gene sequences will be synthesised. DNA cloned directly from human and other mammalian DNA contains many introns and is difficult to work with, since it is often much larger than the cDNA, and crucially will not form the appropriate protein in a bacterium, because of the lack of a mechanism for removing introns in bacteria.

GLOSSARY

ACNFP Advisory Committee on Novel Foods and Processes.

Amino acid The building blocks of protein molecules. There are 20 different kinds of amino acid used to construct proteins.

Bacterial vector A bacterial cell used to carry foreign genetic material into cells in genetic modification.

Casein A protein which occurs as a major constituent of milk.

Cell Mass of living material surrounded by a membrane; the basic structural and functional unit of most organisms.

Chromosome Chemical packages of hereditary information, made up of a single molecule of DNA, tightly coiled and associated with specific proteins.

Cloning The process of replication of a single gene sequence.

Complementary DNA (cDNA) DNA derived from mRNA enzymatically *in vitro* before insertion into a vector.

Cross breeding To interbreed two varieties or breeds of the same species.

DNA Deoxyribonucleic acid, which is present in all living cells and contains the information for cellular structure, organisation and function.

Enzyme A protein which is a biological catalyst. Most metabolic reactions are controlled by enzymes.

Expression A gene is expressed in a cell when the protein encoded by the gene is actively produced in the cell.

FAC Food Advisory Committee.

Gene The basic unit of heredity; an ordered sequence of nucleotide bases, comprising a segment of DNA. A gene contains the sequence of DNA that encodes one protein chain (via RNA).

Genetic modification The manipulation of an organism's hereditary material using artificial techniques with the aim of incorporating or deleting specific characteristics into or from the organism.

Genome The genetic endowment of an organism or individual.

Germ line Germ line cells are those which are, or eventually produce, reproductive cells (gametes).

GM food Shorthand for any food whose production has involved the use of genetic modification at some stage.

Heredity The relation between successive generations, by which characteristics or traits are inherited.

Host The organism into which donor DNA is inserted.

Insulin A protein hormone, secreted by specialised cells of the pancreas, that promotes the uptake of glucose by cells, thereby regulating its concentration in the blood. A deficiency of insulin in the body (*diabetes mellitus*) can be treated by insulin injections.

Insulin-like Growth Factor (IGF) Small protein hormone, produced by a number of tissues, and involved in cell division and tissue development.

Introns Regions within genes that do not code for protein sequences, separated by coding regions known as exons. During transcription (a stage of protein synthesis) the non-coding sequences are excised and the exons "spliced" together.

In vitro Literally, in glass; pertaining to a biological reaction taking place in an artificial apparatus; sometimes used to include the growth of cells from multicellular organisms under cell culture conditions. *In vitro* diagnostic products are products used to diagnose disease outside of the body after a sample has been taken from the body.

Lysine Amino acid common in animals but less so in plants.

Messenger RNA (mRNA) Molecules of ribonucleic acid which carry information from genes which are contained in the nucleus to the protein-synthesising machinery located in the body of the cell.

Micro-injection The technique of introducing very small amounts of material (DNA or RNA molecules, enzymes, etc.) into an intact cell through a microscopic needle penetrating the cell membrane.

Micro-organism Microscopic living entity; micro-organisms can be viruses, prokaryotes (e.g. bacteria) or eukaryotes (e.g. fungi). Also referred to as microbes.

Molecule A chemical entity consisting of two or more atoms bound together.

Nucleotide The building blocks of DNA. The arrangement of the four distinct types of nucleotide within the DNA molecule is responsible for its information storage properties.

Organism Any biological entity, cellular or non-cellular, with capacity for self-perpetuation and response to evolutionary forces; includes plants, animals, fungi, bacteria and viruses.

Phenotype Appearance and behaviour of an organism resulting from the interaction between its genetic constitution and its environment.

Pheromone A natural chemical attractant, or repellent.

Plasmid An extra-chromosomal, self-replicating, circular segment of DNA.

Protein An organic compound resulting from the linking together of many amino acids.

Reverse transcriptase A unique DNA manufacturing enzyme since it uses mRNA, not DNA, as a template to make a complementary (cDNA) strand.

Selective breeding The use of organisms exhibiting desired characteristics to produce offspring which also bear those characteristics.

Transformation The uptake and chromosomal integration of extraneous DNA by certain bacterial or other cells resulting in the acquirement of new characteristics.

Transgene A gene which has been incorporated into a new host.

Transgenic A transgenic organism is one in which foreign genetic material has been incorporated into the recipient's genome.

Vector A plasmid or virus, capable of replication, used to carry "foreign" genetic material into cells in genetic modification.

Viral vector A virus particle used to carry foreign genetic material into cells in genetic modification.

Printed in the United Kingdom for HMSO.
Dd.0297232. 9/93. C20. 3396/4. 5673. 257874.

This report contains the results of a study of the ethical concerns that may arise when consumers are faced with genetically modified foods.

Genetic modification involves the transfer of genetic material between different organisms by artificial means and is being used on an increasing scale in the health and agricultural fields. The report explains what is involved in genetic modification and describes the outcome of consultations with a wide range of religious, consumer and other representative groups and its implications for the food chain. For example some vegetarians may wish to avoid foods containing genes of animal origin. The ethical issues raised by genetically modified foods are addressed and a number of recommendations made to Government and others.

HMSO

HMSO publications are available from:

HMSO Publications Centre
(Mail, fax and telephone orders only)
PO Box 276, London, SW8 5DT
Telephone orders 071-873 9090
General enquiries 071-873 0011
(queuing system in operation for both numbers)
Fax orders 071-873 8200

HMSO Bookshops
49 High Holborn, London, WC1V 6HB
(counter service only)
071-873 0011 Fax 071-873 8200
258 Broad Street, Birmingham, B1 2HE
021-643 3740 Fax 021-643 6510
33 Wine Street, Bristol, BS1 2BQ
0272 264306 Fax 0272 294515
9-21 Princess Street, Manchester, M60 8AS
061-834 7201 Fax 061-833 0634
16 Arthur Street, Belfast, BT1 4GD
0232 238451 Fax 0232 235401
71 Lothian Road, Edinburgh, EH3 9AZ
031-228 4181 Fax 031-229 2734

HMSO's Accredited Agents
(see Yellow Pages)

and through good booksellers

£7.95 net

ISBN 0-11-242954-8

9 780112 429548

ort of the Committee on the Ethics of Genetic Modification and Food Use